

California Prescription Drug Pedigree

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Pedigree - Overview

- 2004 legislation passed
- 1/1/2005 legislation enacted and some sections implemented
- 1/1/2007 pedigree implementation

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Pedigree Overview (cont)

- CA Board of Pharmacy may delay implementation of pedigree requirement until 1/1/08
- CA legislature may delay implementation of pharmacy pedigree requirement until 1/1/09

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Pedigree Definition

- Electronic record, containing information regarding each transaction resulting in a change of ownership of a prescription drug, from sale by manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or person furnishing, administering or dispensing the prescription drug

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Electronic Pedigree Requirements

- Prescription Drug information
- Transaction & Source information
- Ownership information
- Certification

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Prescription Drug Information

- Drug name
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration date
- Lot numbers

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Transaction & Source Information

- Source of prescription drug (prior owner)
 - ◆ Business name
 - ◆ State license number, including CA license if required
 - ◆ Principal address of source
- Sales invoice number for transaction
- Date of transaction

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Ownership Information

- For each prior owner of the drug the pedigree must contain
 - ◆ Prescription drug information
 - ◆ Source information
 - ◆ Transaction information
 - ◆ Name and address of each person certifying delivery or receipt of prescription drug

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Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drugs that the information contained in the pedigree is true and accurate

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Related Legislation

- All wholesale distributors selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesale distributors (effective 1/1/06)
- Restrictions on pharmacy furnishing, manufacturers and wholesale distributors (effective 1/1/05)
- Wholesale or pharmacy may not purchase, sell, trade or transfer without receiving or issuing a pedigree (effective 1/1/07)

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Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
 - ◆ Wholesaler/manufacturer from whom drugs acquired
 - ◆ Licensed wholesale reverse distributor
 - ◆ Pharmacy or wholesale in sufficient quantity to alleviate a specific shortage

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Pharmacy Furnishing Requirements (cont)

- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control

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Manufacturer/Wholesale Distributor Restrictions

- ✧ Furnish prescription drugs only to licensed business or prescriber
- ✧ Acquire prescription drugs only from a manufacturer or licensed wholesaler
- ✧ Effective 1/1/07 a wholesaler or pharmacy may not sell trade or transfer a dangerous drug without a pedigree

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